DRAFT 1
The Materials Process
Clarification of the definition of Synthetic
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Justification: This document is a first attempt to help the NOSB develop a clarification on the definition of synthetic. It provides background information for the development of documents that the NOSB may use with other materials to provide an orientation to new Board members regarding the Materials Review Process.

The NOSB defines a synthetic substance as one that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. (OFPA 2103 (21); NOP rule).

Any substance other than those naturally occurring in a plant, animal or mineral is considered synthetic if it is formulated or manufactured by a chemical process.

Extraction[1]

For substances extracted from naturally occurring plants, animals, or mineral sources the substance can be extracted in any manner and with any substance, material, physical process (i.e. centrifugation, heating, chemical solvents, bases and acids) as long as the extraction process does not chemically change the substance that is being extracted.

Formulation

Once a substance is extracted, if it then undergoes a chemical process as it is formulated or manufactured to produce agricultural or handling inputs, it then would be considered a synthetic and would have to be petitioned for inclusion on the National List.

The final part of the definition "except that such term shall not apply to substances created by naturally-occurring biological processes" allows for chemical changes that occur in living cells that which typically are the result of enzymatic reactions. For example, lactic acid is a non-synthetic substance that is the result of lactose (milk sugar) being fermented by the bacterium *Lactobacillus*.

Based on the minutes of the previous NOSB meetings and certification programs that had functional materials review prior to the OFPA and the National Organic Standards, there was much consensus in many materials decisions in considering the question of whether

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[1] Extraction (NOSB, 1995; Austin, Texas); The concentration, separation and removal of a substance from a plant, animal microbiological or mineral source. Materials used in plant crop and animal production may be extracted in any way that does not result in synthetic reaction as defined by 2103(21). The products of any other methods of extraction shall be considered on a case by case basis and reviewed for compatibility under OFPA Sec. 2119 (m) (1-7).

a substance was synthetic or non-synthetic. However, there are a small number of substances--the majority of which are substances that are extracted from naturally occurring plants, animals, or mineral sources--where the determination of synthetic verses non-synthetic was more strongly debated. The debate centers around the difficultly in determining what constitutes a chemical change. For example, ethanol can be naturally fermented or be synthesized.

In an effort to provide guidance to the NOSB in developing the determination of chemical change, the following information has been gathered from a number of chemistry textbooks which outline the principles of chemistry, chemical reactions and definitions of terms commonly associated with chemical properties of substances.

Basic Chemistry 101 for the NOSB

The science of chemistry deals with the structure of matter--material things--and the changes that matter undergoes. Matter can exist in any size, shape, or color. It is solid, liquid, or gas; living or nonliving. Chemistry seeks to identify the simplest parts of matter; how they are separated and purified; how they are put together; how they are rearranged to produce new forms of matter; and what energy is absorbed or released when such rearrangements are made (Matta and Wilbraham, 1986). A distinction should be made between chemical and physical changes. The OFPA and NOS definition of synthetic specifically mentions chemical change but not physical change. A physical property is a quality or condition of a substance that can be observed or measured without changing the substance's composition. It can be specified without reference to any other substance. Other physical properties of matter include color, solubility, mass, odor, hardness, density, electrical conductivity, magnetism, melting point and boiling point. Physical properties help chemists identify substances (Matta and Wilbraham, 1986). When contractors are hired to technical review of substances for the NOSB and USDA/NOP, they typically list the physical properties of the substances in their review because this is the common way in which substances are described.

Physical changes may result when the temperature of a substance changes. Raising the temperature of a solid may turn it into a liquid (i.e., ice turns into water). A conversion without causing a change in the composition of the substance is called a physical change (Matta and Wilbraham, 1986). When ice undergoes the physical change of melting, this change does not change the nature of water. The physical properties are the same for water that has been frozen and melted as for water that has been converted into steam and then condensed (Matta and Wilbraham, 1986). Historically, the organic industry and the NOSB have acknowledged that physical changes do not render a substance synthetic.

However, there are some substances that have been identified where high temperatures during manufacturing do engender a chemical change in the substance. An example is mined minerals. Historically, the industry and NOSB has recognized that burning or excessive heating of mined mineral is considered to render them synthetic. Formerly, NOSB defined mined minerals as any naturally-occurring non-living substance derived from the earth or water. A mined mineral cannot have undergone molecular change through heating, acidification, basification or fortification with synthetic materials

(NOSB Final Recommendation Addendum Number 25, Definitions and Interpretations, Austin, Texas, 1995). Therefore, heat can alter the physical properties of a substance and for other substances act as a catalyst in chemical reactions or change.

In a chemical reaction, the starting substance or substances, referred to as reactants, are changed into new substances or products. Chemists use an arrow as a shorthand form of the phrase “are changed into”; reactants → products (Matta and Wilbraham, 1986). An example to distinguish between physical and chemical changes is illustrated when sulfur (a solid) is added to iron filings (a solid). They may be separated unchanged from a mixture of the two substances mixed together. This separation is an example of a physical change. If the mixture of these two substances is heated, a chemical change takes place and the sulfur and iron are changed into a nonmagnetic substance, iron sulfide: Iron + Sulfur→ Iron Sulfide (Matta and Wilbraham, 1986). A substances’ composition and behavior in chemical reactions--its chemical reactivity--comprise its chemical properties.

What is a substance?

In chemistry, a pure **substance** is a homogenous material that has a definite chemical composition throughout. There are two kinds of pure substances. One kind can be decomposed into two or more different substances by simple chemical change; these are called **compounds**. There are many millions of compounds.
An example of a compound is pure table salt, which can be decomposed into sodium and chlorine by an appropriate process. Many of the substances on the National Lists of Synthetic substances allowed for use in organic crop and livestock production (Sections 205.601 and 205.603) are compounds. Examples include: isopropanol, chlorine dioxide, ammonium carbonate, lime sulfur and copper sulfate.

The second kind of pure substances are called **elements**, which cannot be decomposed by chemical change. There are 90 natural elements, examples are gold, copper, oxygen, sulfur and hydrogen. Elements cannot be separated into simpler substances by chemical reactions. An example of an element on the National List is sulfur (elemental) for crop production (205.601(e)(3))(Boikess and Edelson, 1978).

Mixtures consist of a physical blend or two or more substances in which the combined substances retain their identity. Most materials found in nature are mixtures. Mixtures can be either homogeneous (same composition throughout) or heterogeneous (has non-uniform composition). A **solution** is a type of a mixture where there is a homogeneous combination of different substances. The difference between a heterogeneous mixture and a solution is that any sample of a solution has the same composition, while the composition of a mixture is not the same throughout. Solutions may be gaseous, liquid or solid. Examples of mixtures on the National List are aquatic plants and fish emulsions. The various compounds and elements that make up these products are within the plant, animal or mineral. When a particular component of the plant is desired for use in an agricultural input it typically has to be extracted and in many cases undergo additional chemical reactions to make it into a substance that is functional when combined with other substances.

A distinction should be drawn between a mixture and a compound**.** ***The elements making up a compound cannot be recovered without a chemical change.*** The substances making up a mixture or solution can. Some mixtures can be separated into their various components by simple physical methods. An example is a gray-colored mixture produced by stirring together powdered yellow sulfur and black iron filings. The individual particles of sulfur and iron can be readily distinguished from one another under a microscope. The mixture is easy to separate because the iron filings can be removed from the mixture with a magnet leaving sulfur behind. Both the sulfur and the iron are unchanged in composition (example from Matta and Wilbraham, 1986).

The substances making up a mixture or a solution need not be elements. For example, one can prepare a solution by dissolving salt, a compound, in water another compound. In addition, the substances making up a mixture or a solution can be combined in varying proportions. The elements in a compound have fixed proportions. (paragraph found in Boikess and Edelson, 1978). Main groups of compounds can be classified based on similar chemical properties. The following are descriptions of each group (Boikess and Edelson , 1978).

Salts: a compound of a metal and nonmetal, or of a metal with a negative polyatomic group. Compounds that have an ammonium group (NH_4^+) instead of a metal are also classified as salts. Some salts are NaCl, KCl, $KMnO_4$ and NH_4Cl. A salt is an ionic solid a room temperature. Most have two ionic components (a) a cation, which can be a polyatomic group such as ammonium or a monoatomic metal such as Na^+, K^+, Ca^{2+} or Mn^{3+} and (b) an anion, which can be a negative polyatomic group or a monoatomic ion such as Cl^- or NH_3^-. A solid salt consists of ions in close association. When the salt dissolves in water, the ions are separated. Substances that exist as ions in solution are called electrolytes. When NaCl dissolves in water, the correct formula is $Na^+ + Cl^-$. This formula treats the component ions of the salts as independent entities, which is approximately how they behave in water solution. Salts are called strong electrolytes because they usually separate completely into ions in water. (Boyd text)

Acids: a compound that is a source of H^+ ions. An acid is usually a compound of hydrogen and a nonmetal or a negative polyatomic group. Unlike salts, acids usually are not aggregates of ions. An acid may be a gas (hydrochloric), liquid (sulfuric) or a solid (oxalic). Like salts, acids tend to form ions when the dissolve in water. When a substance separates into ions it is said to dissociate. Some acids dissociate completely and are called strong acids. Most acids dissociate only partially when dissolved in water. These are called weak acids, they are weak electrolytes.

Bases: a compound that is a source of OH^- ions in water solution. A compound of a cation and the OH^- anion is a base. Bases resemble salts in many ways. They are ionic solids that dissociate into ions when dissolved in water. Bases that contain a cation and OH^- are generally dissociate completely in water and are classified as strong bases. Some strong bases are NaOH (sodium hydroxide) and KOH (potassium hydroxide). Compounds that do not contain hydroxide ions are defined as bases if they produce OH^-

ions by reaction with water. An example is ammonia (NH_3) which reacts with water to produce hydroxide ions.

Nonelectrolytes: Compounds containing only nonmetals usually exist as discrete molecules, rather than collections of ions. These compounds do not dissociate into ions when they dissolve in water. Many organic compounds are nonelectrolytes and they will not dissolve appreciably in water i.e. oil. Some will dissolve in water, although they will not dissociate into ions i.e. sugar, and ethyl alcohol.

Oxides: is a binary compound of any element with oxygen, when the oxygen has an oxidation number of $^{-2}$. Almost every element forms at least on oxide. The properties of oxides vary widely- depending on the element they may resemble a salt, acid, base or non electrolyte.

What constitutes a chemical change?

The chemical properties of a substance are those that describe the way in which it can undergo change, either alone or in interactions with other substances, to form different materials. Such changes are called chemical reactions. The chemical properties that are characteristic of any substance can be described- iron combines readily with oxygen to form the compound called rust. (Boikess and Edelson, 1978). The following are common types of chemical reactions that describe what is happening when different substances and compounds interact (Boikess and Edelson ,1978).

1. Addition or combination reaction: Two substances combine to form one: $2Na+Cl_2$----2NaCl
2. Decomposition reactions: One compound breaks into two or more compounds or elements. $CaCO_3$-------CaO + CO_2
3. Displacement reactions: Substances exchange parts. There are many types of these reactions but one of the most important is called metathesis which is the exchange of ions by two ionic compounds, with the anion of one compound joining the cation of the other compound and vice versa. AB+CD-→AD + CB

    1. Hydrolysis is a displacement reaction of a substance or ion with water. Water is a source of both H^+ and OH^- ions. The OH^- anion combines with the positive portion of the compound that is hydrolyzed. This positive portion may be a cation or an atom with a positive oxidation number. The H^+ cation combines with the negative portion of the compound, which may be an anion or an atom with a negative oxidation number.

    2. Acid-base reaction: an acid is a substance that can donate a proton, and a base is a substance that can accept a proton.

Since many materials used in organic agriculture are derived from plants and animals it is important to mention chemical reactions that occur in by products of these organisms. In living organisms, enzymes play the role in catalyzing a specific reaction or type of reactions. Proteins are substances extracted from living organisms that maybe utilized in materials that are petitioned for use in organic production. Proteins are sensitive to relatively small changes in pH, temperature, or solvent composition may cause them to denature. Denaturation causes physical change, the most observable result is loss of biological activity. Except for cleavage of disulfide bonds, denaturation stems from changes in secondary, tertiary, or quaternary structures through disruption of noncovalent interactions, such as hydrogen bonds, salt linkages and hydrophobic reactions. Common denaturing agents include the following:

1. Heat--most become denatured when heated above 50-60 degrees C.
2. Large changes in pH--adding concentrated acid or alkali to a protein in a aqueous solution causes changes in the charged character of ionizable side chains and interferes with salt linkages.
3. Detergents--treating a protein with sodium dodecylsulfate (SDS), a detergent, causes the native conformation to unfold and exposes the nonpolar protein side chains to the aqueous environment. These side chains are then stabilized by hydrophobic interaction with hydrocarbon chains of the detergent.
4. Organic Solvents- such as alcohols, acetone or ether.
5. Mechanical treatment. Most globular proteins denatured in aqueous solution if they are stirred or shaken vigorously.
6. Urea and guanidine hydrochloride- These substances can cause disruption of protein hydrogen bonding and hydrophobic interactions.

Denaturation can be partial or complete. It can also be reversible or irreversible. Irreversible denaturation causes a fundamental change in the protein, in particular destroying any physiological (biological) activity. In the case of reversible denaturation, the change may only be temporary (Brown, 1988).

The Materials Committee needs to analyze the definitions and technical information provided above and develop a document that can serve as guidance to NOSB members, petitioners and the public that will further clarify the definition of synthetic.

References:

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Matta, Michael, and Wilbraham, A.C. General, Organic and Biological Chemistry. Benjamin/Cummings Publishing Company, California, 1986.